

# Sustaining Positive Engagement and Recovery (SUPEREDEN) - Improving social recovery in young people with emerging severe social disability

<b>Submission date</b> 26/06/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/06/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/02/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Psychosis is a mental health problem that causes people to lose contact with reality, and can involve hallucinations or delusions. Social recovery is a return to effective social functioning after treatment (engaging in constructive leisure and social activity and return to education or work). Cognitive behavioural therapy (CBT) is a talking therapy that is most commonly used to treat anxiety and depression, but can be useful for other mental health problems. The aim of this study is to assess whether Social Recovery Orientated Cognitive Behavioural Therapy (SRCBT) increases the time patients spend in structured activity and reduces their levels of depression and hopelessness.

### Who can participate?

150 patients with non-affective psychosis (psychosis that is not related to emotions or moods)

### What does the study involve?

Participants are randomly allocated to either the control or the experimental group. The experimental group receive regular SRCBT for 9 months. The control group receive treatment as usual. All participants are assessed at the start of the study and after 9 and 15 months.

### What are the possible benefits and risks of participating?

We have found from previous studies that most participants welcome participation in research studies, as even contact with the researchers conducting assessments offers support from concerned and trained professionals above that provided in standard care. This is potentially a very important study which could have important implications for clinical practice in mental health services.

Where is the study run from?

The study is sponsored by Birmingham and Solihull Mental Health NHS Foundation trust (BSMHFT) and recruitment will take place in Birmingham, Norfolk and Lancashire Early Intervention Services.

When is the study starting and how long is it expected to run for?

July 2012 to March 2014

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Linda McCarthy

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

8645

## Study information

### Scientific Title

Sustaining Positive Engagement and Recovery (SUPEREDEN) - the next step after Early Intervention for Psychosis. Study 3: Improving social recovery in young people with emerging severe social disability: A proof of principle randomised controlled trial

**Acronym**

SuperEDEN 3

**Study objectives**

The aim will be to assess the feasibility of Social Recovery orientated Cognitive Behavioural Therapy in a large multicentre trial.

Primary hypothesis:

The intervention will lead to improvements in the time spent in structured activity.

Secondary hypotheses that the intervention will:

1. Reduce levels of depression and hopelessness and
2. Improve negative symptoms

A detailed analysis of adherence will help clarify details of training and supervision and assess the ability of staff from different professional backgrounds to apply this intervention across centres.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee West Midlands The Black Country, 10/04/2012, ref: 05/Q0102/44MHRNC

**Study design**

Randomised; Interventional; Design type: Process of Care, Treatment

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Topic: Mental Health Research Network; Subtopic: Psychosis; Disease: Psychosis

**Interventions**

Three UK sites will be taking part: Birmingham, Lancashire and Norwich.

Participants will be randomly allocated to two groups:

1. Social Recovery Orientated Cognitive Behavioural Therapy + Treatment As Usual (SRCBT +

TAU)

## 2. TAU only

Participants randomly allocated to the SRCBT + TAU group will receive SRCBT over 9 months by a qualified psychologist or an accredited CBT therapist. Sessions will be held either weekly or fortnightly and the therapy will be delivered in 3 stages.

Follow Up Length: 15 month(s)

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome measure

Time Use Survey (Short, 2006) assessed at 9 and 15 months

### Secondary outcome measures

The Positive and Negative Syndrome Scale (PANSS)

### Overall study start date

01/07/2012

### Completion date

31/03/2014

## Eligibility

### Key inclusion criteria

1. Patients with non-affective psychosis
2. Clients of Norfolk, Birmingham and Lancashire early intervention services
3. Clients who show a low level of structured activity after at least one year of treatment (defined as 30 hours or less per week)
4. Clients who have been with EIS between one and two years
5. Male & Female; Upper Age Limit 35 years ; Lower Age Limit 16 years

### Participant type(s)

Patient

### Age group

Adult

### Sex

Both

### Target number of participants

Planned Sample Size: 150; UK Sample Size: 150

### Key exclusion criteria

1. Clients who were part of the original National EDEN Cohort
2. Clients who do not speak English
3. Clients who are considered too unwell by their care coordinators will not be approached by the study team

**Date of first enrolment**

01/07/2012

**Date of final enrolment**

31/03/2014

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**School of Psychology**

Birmingham

United Kingdom

B15 2TT

## **Sponsor information**

**Organisation**

Birmingham and Solihull Mental Health NHS Foundation Trust (UK)

**Sponsor details**

Research & Innovation, Radclyffe House

66-68 Hagley Road

Birmingham

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**Sponsor type**

Charity

**ROR**

<https://ror.org/00cjeg736>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Programme Grants for Applied Research; Grant Codes: RP-PG-0109-10074

**Alternative Name(s)**

NIHR Programme Grants for Applied Research, PGfAR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2018		Yes	No